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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|----------------|-----------------------|-------------------------|-------------------------|--|
| 09/941,327 | 08/29/2001 | Swaminathan Jayaraman | 638.45 | 6222 | |
| 33771 75 | 590 01/15/2004 | | EXAMINER | | |
| PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, | | | BUI, VY Q | | |
| GUTMAN, BONGINI, & BIANCO P.L. 601 BRICKELL KEY DRIVE, SUITE 404 | | | ART UNIT | PAPER NUMBER | |
| MIAMI, FL 3 | 3131 | | 3731 | 9 | |
| | | | DATE MAILED: 01/15/2004 | DATE MAILED: 01/15/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | 7 | | | |
|---|---|--|---|--|--|--|
| | 09/941,327 | JAYARAMAN, SWAMINATHAN | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Vy Q. Bui | 3731 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 36(a). In no event, however, may a reply be timer within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| 1) Responsive to communication(s) filed on 28 Oc | <u>ctober 2003</u> . | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This | action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1,2,12-17 and 23-36 is/are pending in the application. 4a) Of the above claim(s) 12,17,27,30 and 33 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1,2,13-15,23-26,28,29,31,32 and 34-36 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex | epted or b) objected to by the Idrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list 13) Acknowledgment is made of a claim for domestic since a specific reference was included in the first 37 CFR 1.78. a) The translation of the foreign language pro 14) Acknowledgment is made of a claim for domestic reference was included in the first sentence of the | s have been received. s have been received in Applicativity documents have been received in Applicativity documents have been received (PCT Rule 17.2(a)). of the certified copies not received priority under 35 U.S.C. § 119(ast sentence of the specification or evisional application has been received priority under 35 U.S.C. §§ 120 | on No ed in this National Stage ed. e) (to a provisional application) in an Application Data Sheet. eived. and/or 121 since a specific | | | | |
| Attachment(s) | _ | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. | 5) Notice of Informal P | (PTO-413) Paper No(s) atent Application (PTO-152) | | | | |

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DETAILED ACTION

Election/Restrictions

Claims 12, 17, 27, 30, 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species 11 shown in Fig. 13, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the coating layers must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 25, 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to fully appreciate the invention commensurate in scope with these claims. The specification does not provide any definition for the recitations "closed cells" and "open cells". Although the drawings provide some examples for "closed cells" and "open cells", there is no definition for the recitations. For one of ordinary skill in the art, a cell is conventionally considered as a radial opening and the struts that enclosed the opening. Without any definition in the specification, it is not possible to appreciate what is covered by the recitation "open cells".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by PENN et al. (6,375,677).

As to claims 23, 25-26, PENN (Figs. 3 and 12a-12i) shows a stent having every limitations as recited in the claims such as one pattern at both ends and another different pattern in the mid section, linear struts between patterns, the mid section includes articulations 270.

As to claim 24, PENN (Figs. 12a-12i) shows some undulating members of the stent.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 13-15, 28-29, 31-32, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over PENN et al. (6,375,677) in view of CALLOL et al. (6,174,329).

As to claims 1-2, 14, 28-29, 31-32, 34, 36, PENN discloses substantially all the limitations in the claims, except for two layers of coatings not more than 10 microns. CALLOL (claims 1 and 4) discloses a stent having an inner coating layer of a thickness from 0.01 to 25 microns and an outer coating layers of a thickness from 1.0 to 50 microns. Because there is no specific name for a biological substance in the claim, inner and outer layers of the coatings, which are of biological compatible substances and therefore can be considered in a broad sense as biological substances.

As to claim 13, PENN and CALLOL do not disclose both coatings are of a radiopaque substance. However, it is just a matter of design choice to have two coatings of a radiopaque material.

As to claim 15, PENN and CALLOL do not disclose both coatings are of a polymeric substance. However, it is just a matter of design choice to have two coatings of a polymeric substance.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-

0858.

VQB

1/8/2004